



founded 1881

January 15, 2015

Pharmaceutical Working Group
C/o Angelo J. Bellomo, REHS, QEP
Deputy Director for Health Protection
5050 Commerce Drive
Baldwin Park, CA 91706

Re: Los Angeles County Pharmaceuticals and Sharps Collection and Disposal
Stewardship Ordinance

Dear Angelo,

On behalf of the Consumer Healthcare Products Association (CHPA), a 134 year-old trade association representing the manufacturers of over-the-counter (OTC) medicines and dietary supplements, I'm writing you today to oppose the latest draft Los Angeles County Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance released for public comment on January 5th. While our industry agrees that Los Angeles County residents should know the proper way of disposing their expired or unwanted medications, we disagree that an inefficient, ineffective, expensive, unworkable drug take back ordinance is the best path forward for Los Angeles County.

OTC medicines play an important role in our nation's overall healthcare. Our members' products provide millions of Americans – including millions of Los Angeles County residents – with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases. These medicines are affordably accessible to patients, and help empower families to treat conditions with trusted, Food and Drug Administration (FDA) approved treatments. According to a recent study by Booz and Company, for every dollar spent on an OTC medicine, we save the U.S. Healthcare system \$6-\$7.¹ Without access to OTC medicine, over 60 million Americans would not seek treatment for their ailments at all.²

For these reasons, we take very seriously any potential disruption - regulation or otherwise- to the affordability of OTC healthcare. As the first and only line of

¹ The Value Of OTC Medicine To The United States, Booz & Co., January 2012.

² Ibid

defense for many Los Angeles County families, it is critical that county officials evaluate the opportunity cost (cost of medications vs. benefits of drug take back) associated with the implementation of a mandatory, manufacturer funded drug take back program.

Regulated Industry Input

After participating for months as a member of the technical advisory group (TAG) and after providing ample comments on the first draft of this Pharmaceuticals and Sharps Collection and Disposal Ordinance, it was very disappointing to see that industry input was so widely ignored. Most of the concerns we expressed on the initial draft remain within this second draft. While the draft ordinance suggests the goals of the legislation are twofold: 1) allow for the safe, convenient and sustainable collection and disposal of unwanted drugs and sharps by county residents and 2) protects, maintains, restores, and/or enhances the environment and its natural resources; it is clear that that county staff is instead intent on drafting an extended producer responsibility (EPR) ordinance regardless of the input by the affected parties or the set goals. Given the lackluster performance of pharmaceutical take back programs in the United States and around the globe, the goals set forth in this ordinance and the ordinance itself are mutually exclusive ideals.

Science Matters

As expressed in our previous comments, very little evidence/science was presented to the TAG as reasoning behind the suggested legislation. To this day, we (the regulated industry) have not been presented with any scientific evidence that suggests trace pharmaceuticals in the water supply are a result of improper disposal, nor have we been shown proof that the proposed EPR ordinance would have any impact on pharmaceuticals in the water – most of which is getting there from natural human excretion. Similarly, county staff has yet to demonstrate how an EPR ordinance would address Los Angeles County's drug abuse issues. As we have stated time and time again, the OTC industry is not opposed to addressing improper disposal, and safe storage of pharmaceuticals. Nor are we against limiting the improper use and abuse of our medications. We are simply opposed to a program which will do little to address either while severely risking access to affordable treatments for Los Angeles County residents who can least afford it.

Draft Ordinance

The latest draft ordinance differs little from the first draft. It still lacks shared responsibility, conflicts with federal anti-kickback laws, and is absent of accountability and measurable output that accomplishes its stated goals. Worse still, as more program specifics were revealed in the current draft it is clear the proposal is even less workable than initially anticipated. Collection point mandates are unrealistic, and do not account for the lack of participation by collectors in other jurisdictions in California.

Education Is More Effective

As I communicated to you in a personal meeting last week, CHPA – along with the pharmaceutical/sharps trade associations and the retail community – are prepared

to support and fully fund an education and awareness program to ensure LA County residents are informed about safe medicine use, storage, and disposal. We believe strongly that this approach is the best path forward for Los Angeles County in effectively altering patient/consumer behavior as it relates to safe medicine/sharps disposal; something the proposed draft ordinance will not accomplish.

The OTC industry has extensive experience educating our end customers and our programs have garnered tangible, measurable, impressive results.

Conclusion

The OTC industry remains committed to the cause of educating our customers about the proper techniques of safe medicine storage and disposal. Rather than engaging in an unworkable, ineffective drug take back program, CHPA hopes to work in partnership with County staff and Supervisorial offices on an education and awareness program which would do far more to address drug disposal, diversion and abuse among LA County residents.

Thank you for your consideration.

Best Regards,



Carlos I. Gutiérrez
Senior Director and Head of State Government Affairs
Consumer Healthcare Products Association
Washington, D.C., 20006

Cc: Supervisor Michael D. Antonovich
Supervisor Don Knabe
Supervisor Sheila Kuehl
Supervisor Mark Ridley-Thomas
Supervisor Hilda L. Solis



founded 1881

November 30, 2015

Pharmaceutical Working Group
C/o Angelo J. Bellomo, REHS, QEP
Deputy Director for Health Protection
5050 Commerce Drive
Baldwin Park, CA 91706

Re: Los Angeles County Pharmaceuticals and Sharps Collection and Disposal
Stewardship Ordinance

Dear Angelo,

On behalf of the Consumer Healthcare Products Association (CHPA), a 134 year-old trade association representing the manufacturers of over-the-counter (OTC) medicines and dietary supplements, I'm writing you today to oppose the draft Los Angeles County Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance and express concern with the process used to arrive at this proposal. While our industry agrees that Los Angeles County residents should know the proper way of disposing their expired or unwanted medications, we disagree that an inefficient, ineffective, expensive, unworkable drug take back ordinance is the best path forward for Los Angeles County.

OTC medicines play an important role in our nation's overall healthcare. Our members' products provide millions of Americans – including millions of Los Angeles County residents – with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases. These medicines are affordably accessible to patients, and help empower families to treat conditions with trusted, Food and Drug Administration (FDA) approved treatments. According to a recent study by Booz and Company, for every dollar spent on an OTC medicine, we save the U.S. Healthcare system \$6-\$7.¹ Without access to OTC medicine, over 60 million Americans would not seek treatment for their ailments at all.²

For these reasons, we take very seriously any potential disruption - regulation or otherwise- to the affordability of OTC healthcare. As the first and only line of

¹ The Value Of OTC Medicine To The United States, Booz & Co., January 2012.

² Ibid

defense for many Los Angeles County families, it is critical that county officials evaluate the opportunity cost (cost of medications vs. benefits of drug take back) associated with the implementation of a mandatory, manufacturer funded drug take back program.

Board of Supervisors Motion

On June 2, 2015, the Los Angeles County Board of Supervisors approved a motion introduced by Supervisor Antonovich which directed county staff to among other things “investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County.” The County staff then formed a “Working Group” to evaluate the feasibility of adopting an ordinance similar to the pharmaceutical waste take back ordinances adopted by various Bay Area counties.

Disappointingly, the Working Group never once attempted to consult with the OTC industry about our perspective in adhering to the ordinances passed in other counties within California prior to making their recommendation to the Board that a take back ordinance was indeed “feasible” within Los Angeles County. Since pharmaceutical manufacturers are mandated to design, implement, deploy, and maintain the take back programs currently passed in California, input on practicality and other concerns would have been valuable information for the Working Group to seek and consider before making a feasibility recommendation to the Board of Supervisors.

Fortunately, on August 11, the Board of Supervisors adopted an amendment to the original motion introduced by Supervisor Knabe which directed county staff to convene a stakeholder process **FIRST** before an ordinance is drafted as the “stakeholder process carries a great deal of value and thus should be conducted first.”³ The sentiment behind this amendment was further clarified during discussion and testimony prior to the eventual vote by the Supervisors. The approval of the amendment ultimately directed county staff to have the stakeholder process before an ordinance is drafted during which time all potential solutions on this issue were to be discussed and considered.

The Process

In response to the amended motion, the Los Angeles County staff created the Technical Advisory Group (TAG) as a way for county staff to hear concerns from all affected stakeholders prior to drafting an ordinance. From the opening meeting of the TAG, however, it was clear that county staff was intent on drafting an extended producer responsibility (EPR) ordinance regardless of the input by the affected parties. This was especially demonstrated by the fact that we (TAG) as a group were never equipped with clearly defined goals for a potential ordinance/program to solve. According to documents produced by county staff, the goal of the TAG meetings and eventual ordinance was to promote extended producer

³ <http://file.lacounty.gov/bos/supdocs/96645.pdf>

responsibility principles.⁴ This goal, however, contradicts statements you made in an interview with KPCC on November 13, 2015 where you were quoted as suggesting the goal of this ordinance/effort to be more about environmental and public safety concerns – not simply the promotion of EPR principles.⁵ As you might imagine, concrete, agreed upon goals are a crucial component to fruitful, engaging discussions within the TAG on this issue. Promotion of EPR principles, at least as they relate to pharmaceuticals, and environmental/public safety improvements, are in many ways mutually exclusive ideals. Furthermore, if the TAG was created to discuss best practices and feedback on existing EPR ordinances (as was outlined in the Objective, Goals, and Purpose document produced by staff indicates⁶), why then were none of our concerns and feedback heeded in the draft ordinance?

Science and Data

As with most public policy issues, the use of science and data is important in both identifying the nature and scope of a problem and in coming up with a workable solution. Unfortunately, both science and data were noticeably absent during our four TAG meetings that led to the first draft of the EPR ordinance. According to Dr. Gunzenhauser, Interim Health Officer for Los Angeles County, the principle behind a pharmaceutical take back ordinance is to “protect public health and assure public safety⁷.” Over the course of the last few months, proponents of an ordinance – including public health staff – have expressed concern over drug related deaths, accidental poisonings, and trace pharmaceuticals in the water supply. Yet, no research or data was ever presented to the TAG to demonstrate that a drug take back ordinance would resolve any of these issues. Additionally, no evidence was ever presented to suggest that trace pharmaceuticals in the water supply are a result of improper disposal.

Pharmaceuticals In The Water Supply

On the contrary, the World Health Organization says pharmaceuticals are present in trace concentrations in water sources as a result of wastewater effluents.⁸ That is, the vast majority (around 90%) of pharmaceuticals in the water supply arrive there due to human use and excretion. Research hydrologist Dana Kolpin of the United States Geological Survey explains that the only reason we are finding more pharmaceuticals in the water today is because we have the instruments to detect them. In the past, scientists could only measure about 19 pharmaceuticals in a 1-liter sample, but today they use a 15 milliliter vial which can measure 110 pharmaceuticals at much more sensitive levels⁹. The level of pharmaceuticals in the water, however, are at such low concentrations that there is no indication they pose a threat to human health. In fact, one of the most widely detected medicines in the water is Ibuprofen measured at 2.5 parts per trillion. At this level, a person

⁴ <http://publichealth.lacounty.gov/docs/EPRSharpOrdinance.pdf>

⁵ <http://www.scprr.org/news/2015/11/13/55621/la-county-looks-to-make-drug-companies-pay-for-dis/>

⁶ <http://publichealth.lacounty.gov/docs/EPRSharpOrdinance.pdf>

⁷ <http://publichealth.lacounty.gov/pharma.htm>

⁸ http://www.who.int/water_sanitation_health/emerging/info_sheet_pharmaceuticals/en/

⁹ <http://www.greenbiz.com/article/downstream-drugs-big-pharmas-big-water-woes>

would have to drink 2 liters a day of water for over 100,000 years to get the equivalent of a single 200mg tablet¹⁰.

Simply put, drug take back programs cannot address the vast majority of pharmaceuticals in the environment. "The main way drug residues enter water systems is by people taking medicines and then naturally passing them through their bodies," says Raanan Bloom, Ph.D., an environmental assessment expert in FDA's Center for Drug Evaluation and Research. Dr. Bloom goes on to say "many drugs are not completely absorbed or metabolized by the body and can enter the environment after passing through waste water treatment plants."

Drug Take Back Ordinances And Drug Abuse

No research was ever provided to the TAG that showed a significant reduction in drug abuse as a result of drug take back laws around the country or elsewhere. This is important to note as drug abuse is one of the primary reasons to pursue a drug take back ordinance according to the Los Angeles County Department of Health EPR web site¹¹. On that same web page, Dr. Gunzenhauser admits that "75% of residents who misuse prescription drugs obtain them from relatives or friends.¹²" In no way will a drug take back ordinance overcome a person's willingness to distribute their own prescription or over-the-counter drugs to a friend or relative. Preventing drug abuse and diversion is more a function of safe storage than it is safe disposal – something the draft ordinance put forth by the Department of Health fails to address.

Draft Ordinance

Lack of Shared Responsibility

Over the course of the last few months as this issue has been debated among stakeholders, a common theme Los Angeles County staff has continuously deemed an important aspect of extended producer responsibility is "shared responsibility." Yet, when reviewing the draft ordinance, shared responsibility is noticeably lacking within any of the program's divisions. Instead, the take back program's only mandate is for medicine manufacturers to produce a stewardship plan, deploy the program, educate the public about the program, reimburse the county for oversight, and be responsible for possible fines, fees, and potential lawsuits associated with complying with the ordinance. Not one other stakeholder or constituency has any responsibility within this draft language to make the program work.

Section 11.050 Stewardship Plans – Collection of Covered Drugs and Sharps makes it clear that producers/manufacturers must provide "reasonably" convenient and equitable access drop off sites within each Supervisorial District, yet in the same section the draft states that "no person is required to serve as a collector in a stewardship plan." As a result, it puts medicine manufacturers in the

¹⁰ Rengao, S. Pharmaceuticals in U.S. Drinking Water and Beyond, Louisville Water Company, referring to AwwaRF Study project #2758

¹¹ <http://publichealth.lacounty.gov/pharma.htm>

¹² <http://publichealth.lacounty.gov/pharma.htm>

position of identifying collectors (or risk being fined for non-compliance), while the County makes it entirely voluntary for people or organizations to serve as a collector. Not even local law enforcement is mandated to participate as a collector. As ordinances that have passed in other areas of California have demonstrated, finding an adequate number of collectors is a major challenge. Reports out of Alameda County – the longest running ordinance in the country – indicate that the program is having difficulty getting off the ground for this very reason. Adding to the complications, the California Board of Pharmacy is considering a new rule that will make participation in drug take back local ordinances in the state entirely voluntary for pharmacies¹³. LA County residents made clear in public testimony that if collection points are scarce, they would likely not take advantage of the take back program. This sentiment is proven in areas of the country and world which have existing programs. For instance, Sweden has had drug take back for over 40 years and is only achieving 43% participation in their program. Clark County, Washington yields less than 0.1% participation in its program¹⁴.

Conflicts with the Federal Anti-Kickback Law

The draft ordinance has a provision under *Section 11.050 Stewardship Plans – Collection of Covered Drugs and Sharps* which states that a collector “may agree to serve as a collector in exchange for incentives or payment offered by a Producer, group of Producers or Stewardship Organization.” This seems to directly conflict with federal anti-kickback laws which prevent pharmacists and companies from accepting payments or inducements to have any potential to induce recommendations for products or services that are reimbursed through a government health care program. While incentives or payments offered by a medicine producer or group of producers to a pharmacy to serve as a take-back collector could be argued to not impact recommendations for products or services, both the paying producers and the receiving pharmacies would have to deal with this using extreme caution to make sure they clearly fall within a safe harbor under the federal anti-kickback statute. As the Department of Health and Human Services (HHS) Office of Inspector General’s fraud and abuse law overview webpage puts it: “The Government does not need to prove patient harm or financial loss to the programs to show that a physician violated the Anti-Kickback Statute. A physician can be guilty of violating the Anti-Kickback Statute even if the physician actually rendered the service and the service was medically necessary. Taking money or gifts from a drug or device company or a durable medical equipment (DME) supplier is not justified by the argument that you would have prescribed that drug or ordered that wheelchair even without a kickback.”¹⁵

Lack of Hazardous Waste Disposal Facilities In California

Section 11.070 Stewardship Plans – Disposal of Covered Drugs and Sharps contains a section which requires that all stewardship plans be disposed of at a

¹³ <http://calpsc.org/mobius/cpsc-content/uploads/2015/11/BoP-Draft-Pharmacy-Take-Back-Regs-for-10-29-2015-Public-Meeting.pdf>

¹⁴ <http://pubs.acs.org/doi/pdf/10.1021/es203987b>

¹⁵ <http://oig.hhs.gov/compliance/physician-education/01laws.asp>

permitted hazardous waste disposal facility as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 264 and 265. Since California has no approved incineration facilities for medical waste, collected medications will require transportation outside of state lines. In fact, according to the stewardship plans approved for use in Alameda County, collected medications are required to be transported via truck across state lines all the way to the state of Missouri for eventual incineration. According to a committee analysis conducted by the California Senate Committee on Environmental Quality on July of 2015, incinerators “are known to release numerous toxic chemicals into the atmosphere and to produce ashes and other solid waste residues that contaminate the air, water, and soil as well as vegetation in the vicinity of the facility.” The analysis continues, “adverse health effects associated with incineration are of great concern as large population groups and workers may be exposed to derived toxic substances. Many of these chemicals are known to be persistent, bio accumulative, carcinogenic, or endocrine disruptors. Populations living near incinerators are potentially exposed to chemicals by way of inhalation of contaminated air, consumption of contaminated foods, water, or dermal contact with contaminated soil.” On top of all this, there are occupational hazards for incinerator workers at these facilities¹⁶.

A recent study conducted by researchers at the University of Michigan conclude that drug take back programs may in fact be worse on the environment than in-home drug disposal as several federal agencies recommend as a method for medicine disposal¹⁷. This draft ordinance in many ways willingly sacrifices the environmental ills associated with out-of-state incineration in favor of a perceived benefit to water quality – though no proof of one exists.

Private Right Of Action

The draft ordinance includes a private right of action provision which isn’t found in any existing ordinance/law in the United States. This section grants the District Attorney, an applicable City Attorney, a Producer, or any organization with tax exempt status and with a primary mission of protecting the environment the ability to bring a civil action to enjoin violations or compel compliance with any requirement of the Chapter or adopted rule or regulation. This exposure to frivolous lawsuits is not a “best practice” adopted by other local governments in the state nor did it ever come up during discussion of the TAG so it is confusing how it made its way into the text of the draft.

Point of Sale Fee

In Section 11.080 Stewardship Plans – Administrative and Operational Costs there is a provision which prevents a producer from charging a point-of-sale fee to consumers to recoup costs of a stewardship plan. The prohibition from charging consumers a user fee appears to be unique solely to pharmaceutical drug take back as it is common practice with other industries like paint, cell phones, tires,

¹⁶ Senate Committee on Environmental Quality Committee Analysis for SB 423, July 6, 2015

¹⁷ <http://pubs.acs.org/doi/pdf/10.1021/es203987b>

televisions, and computers. Consumers of medications play a crucial role in the success of a program. Participation in a program is enhanced when consumers pay for some of the service they are provided. With no “skin in the game,” residents of LA County are less likely to participate in a mandated program and in turn have a significant impact on the ordinance’s intended goal.

Goals For Producers But None For Program Itself

Throughout the draft ordinance there are demands, mandates, and expectations of producers and the stewardship plans they propose and operate within the county. However, there are few to no goals or expectations placed on the ordinance itself. EPR legislation for pharmaceuticals is truly an experiment. Experimental laws should have measurable expectations and include a sunset provision if those goals are not met. As stated before, the Department of Health claims that the need for this ordinance lies in the concern for public health (pharmaceuticals in waterways) and public safety (drug abuse and accidental poisonings). If this ordinance is being pursued to resolve those two issues, then the County should measure the ability of the law to influence those two concerns. Baselines measurements of pharmaceuticals in the water supply, resident participation rates, and drug abuse statistics should be taken before and after the ordinance has been adopted to ensure the law is accomplishing its intended goal. If it does not, then it should sunset and cease as law.

Voter Sentiment

A recent survey by FM3 Public Opinion Research and Strategy indicates that Los Angeles County voters DO NOT consider disposal of expired or unwanted medications to be a serious concern that requires County government intervention. This sentiment was reflected in the very low turnout by the public at the hearings the Department of Public Health held on the ordinance itself. On the other hand, voters DO have a great concern for health care costs as shown by the fact 69% believe a countywide drug take back program would result in Los Angeles County residents paying higher prices for medications.¹⁸ In fact, 1/3 of voters think implementing such a program would result in residents paying “much higher prices” for otherwise affordable medication.¹⁹

Education Is More Effective

When given a choice, Los Angeles County voters opt for medicine manufacturers to work with pharmacies, retailers and county officials to educate residents about how to properly dispose of expired or unwanted medications rather than imposing a requirement that medicine manufacturers fully fund and run a countywide drug take back program.²⁰ Education and awareness has long been the most effective method in dealing with drug diversion and abuse, and as studies indicate is more environmentally friendly than a broad, sparingly used drug take back program. The Los Angeles County Department of Health Substance Abuse Prevention and Control

¹⁸ Los Angeles County Drug Take Back Issues Survey – Summary of Key Findings. Fairbank, Maslin, Maullin, Metz & Associates FM3, November 10, 2015

¹⁹ Ibid.

²⁰ Ibid.

brochure acknowledges this fact. In the brochure's opening message by Los Angeles County Director of Public Health and Health Officer Dr. Jonathan Fielding, he states "we can reduce the burden of this problem by working together to address this growing public health concern through education, training, and other actions to reduce inappropriate access and use²¹." The OTC industry agrees.

The OTC medicine industry has experience building effective educational campaigns. Throughout the last decade, emergency department visits for unsupervised medication exposures in young children were on the rise and peaked in 2010 with more than 60,000 children visiting the emergency department because they got into medicine when no one was looking. The OTC industry, working with the Centers for Disease Control and Prevention, launched Up and Away and Out of Sight, an educational campaign reminding parents and caregivers to keep children safe by storing medicines and vitamins up and away and out of children's sight and reach. Data published this fall in *Pediatrics*, the official journal of the American Academy of Pediatrics, reported that emergency department visits have been declining 7.6% since 2010 – a timeframe that aligns with the launch of our educational campaign.

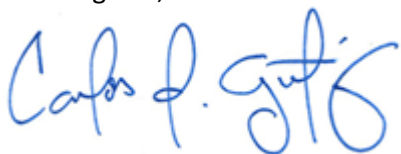
Conclusion

The TAG process from the outset has been a challenging experience. We were hopeful we could use the meetings for a substantive conversation about an identifiable problem and potential solutions to that perceived problem. Instead, discussion revolved almost entirely on creating an EPR ordinance, regardless of existing data, research, and experiences.

Regardless, the OTC industry remains committed to the cause of educating our customers about the proper techniques of safe medicine storage and disposal. Rather than engaging in an unworkable, ineffective drug take back program, CHPA hopes to work in partnership with County staff and Supervisorial offices on an education and awareness program which would do far more to address drug diversion and abuse among LA County residents.

Thank you for your consideration.

Best Regards,



Carlos I. Gutiérrez
Senior Director and Head of State Government Affairs
Consumer Healthcare Products Association
Washington, D.C., 20006

²¹ <http://publichealth.lacounty.gov/docs/HealthNews/PrescriptionDrug-12-13.pdf>

Cc: Supervisor Michael D. Antonovich
Supervisor Don Knabe
Supervisor Sheila Kuehl
Supervisor Mark Ridley-Thomas
Supervisor Hilda L. Solis